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Senju Pharmaceutical Co., Ltd.,
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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SENJU PHARMACEUTICAL CO., LTD.;
BAUSCH & LOMB INCORPORATED; and
BAUSCH & LOMB PHARMA HOLDINGS
CORP.,

Plaintiffs,

v.

AMNEAL PHARMACEUTICALS LLC and
AMNEAL PHARMACEUTICALS INDIA
PVT. LTD.,

Defendants.

Civil Action No. 18-16991

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Senju Pharmaceutical Co., Ltd. (“Senju”), Bausch & Lomb Incorporated (“B+L”) and Bausch & Lomb Pharma Holdings Corp. (“B+L Pharma Holdings”) (collectively, “Plaintiffs”) by way of Complaint against Defendants Amneal Pharmaceuticals LLC (“Amneal LLC”) and Amneal Pharmaceuticals India Pvt. Ltd. (“Amneal Ltd.”) (collectively, “Amneal” or “Defendants”) allege as follows:

THE PARTIES

1. Plaintiff Senju Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Japan, with a principal place of business at 3-1-9, Kawaramachi, Chuo-ku, Osaka 541-0048, Japan.

2. Plaintiff Bausch & Lomb Incorporated (“B+L”) is a corporation organized and existing under the laws of New York, with a place of business at 1400 North Goodman St., Rochester, New York 14609. B+L is the registered holder of approved New Drug Application No. 203168, which covers Prolensa[®].

3. Plaintiff Bausch & Lomb Pharma Holdings Corp. is a corporation organized and existing under the laws of Delaware, with a place of business at 700 Route 202/206, Bridgewater, New Jersey 08807. B+L Pharma Holdings is a wholly-owned subsidiary of B+L.

4. Upon information and belief, Defendant Amneal LLC is a Delaware limited liability company, having its principal place of business at 400 Crossing Blvd, Third Floor, Bridgewater, New Jersey 08807-2863.

5. Upon information and belief, Defendant Amneal Ltd. is a private limited liability company organized and existing under the laws of India, having its principal place of business at 882/1-871, Village: Rajoda, Near Hotel Kankavati, Taluka: Bavla, Ahmedabad-382220, Gujarat, India. Upon information and belief, Amneal Ltd. is a wholly-owned subsidiary of Amneal LLC.

NATURE OF THE ACTION

6. This is an action for infringement of United States Patent No. 10,085,958 (“the ‘958 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Amneal’s filing of an Abbreviated New Drug Application (“ANDA”) under section 505(j) of the Federal Food, Drug,

and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market its generic bromfenac ophthalmic solution 0.07% (“Amneal’s generic bromfenac ophthalmic solution”).

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. Upon information and belief, this Court has jurisdiction over Amneal LLC. Upon information and belief, Amneal LLC is in the business of, *inter alia*, developing, manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Amneal LLC directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Amneal’s generic bromfenac ophthalmic solution. Upon information and belief, Amneal LLC purposefully has conducted and continues to conduct business in this judicial district.

9. Upon information and belief, Amneal LLC is registered to do business in New Jersey under business ID 0600211542.

10. Upon information and belief, Amneal LLC has its principal place of business at 400 Crossing Blvd, Third Floor, Bridgewater, New Jersey 08807-2863, Amneal owns a facility named “Transdermal, Topicals & Complex Oral Solids Manufacturing and R&D” having an address of 1 New England Avenue, Piscataway, New Jersey 08854.

11. Amneal LLC has admitted to, consented to, or has not contested the jurisdiction of this Court in prior District of New Jersey actions, including, for example: *Senju Pharmaceutical Co., Ltd. et al. v. Amneal Pharmaceuticals LLC et al.*, Civil Action No. 3:18-cv-05571; *Forest Laboratories, LLC et al. v. Amneal Pharmaceuticals LLC et al.*, Civil Action No.

2-17-cv-11680; *Sucampo AG et al., v. Amneal Pharmaceuticals LLC*, Civil Action No. 3-17-cv-02577; *AstraZeneca Pharmaceuticals LP et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 1-17-cv-01968; and *Jazz Pharmaceuticals, Inc. et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 17-cv-1440.

12. Amneal LLC has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in prior District of New Jersey actions, including, for example: *Senju Pharmaceutical Co., Ltd. et al. v. Amneal Pharmaceuticals LLC et al.*, Civil Action No. 3:18-cv-05571; *Sucampo AG et al., v. Amneal Pharmaceuticals LLC*, Civil Action No. 3-17-cv-02577; *AstraZeneca Pharmaceuticals LP et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 1-17-cv-01968; *Jazz Pharmaceuticals, Inc. et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 17-cv-1440.

13. Upon information and belief, this Court has jurisdiction over Amneal Ltd. Upon information and belief, Amneal Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Amneal Ltd. directly, or indirectly, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district, and this judicial district is a likely destination for Amneal's generic bromfenac ophthalmic solution. Upon information and belief, Amneal Ltd. purposefully has conducted and continues to conduct business in this judicial district.

14. Amneal Ltd. has admitted to, consented to, or has not contested the jurisdiction of this Court in prior District of New Jersey actions, including, for example: *Senju Pharmaceutical Co., Ltd. et al. v. Amneal Pharmaceuticals LLC et al.*, Civil Action No. 3:18-cv-05571; *Shire Development LLC et al. v. Amneal Pharmaceuticals LLC et al.*, Civil Action No. 1:15-cv-02865;

Otsuka Pharmaceutical Co., Ltd. v. Amneal Pharmaceuticals LLC, Civil Action No. 15-cv-01585; *AstraZeneca Pharmaceuticals LP et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 12-cv-4841.

15. Amneal Ltd. has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in prior District of New Jersey actions, including, for example: *Senju Pharmaceutical Co., Ltd. et al. v. Amneal Pharmaceuticals LLC et al.*, Civil Action No. 3:18-cv-05571; *Shire Development LLC et al. v. Amneal Pharmaceuticals LLC et al.*, Civil Action No. 1:15-cv-02865; *Otsuka Pharmaceutical Co., Ltd. v. Amneal Pharmaceuticals LLC*, Civil Action No. 15-cv-01585; *AstraZeneca Pharmaceuticals LP et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 12-cv-4841.

16. Upon information and belief, Amneal LLC and Amneal Ltd. operate as a single integrated business. The Amneal website states that “[t]he company’s expanding operations in India are an integral part of Amneal’s R&D and manufacturing capabilities and expertise.” See <http://www.amneal.com/international/>.

17. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENT IN SUIT

18. The PTO issued the ’958 patent on October 2, 2018. The ’958 patent claims, *inter alia*, formulations of bromfenac for ophthalmic administration. Plaintiffs hold all substantial rights in the ’958 patent and have the right to sue for infringement thereof. B+L Pharma Holdings is the assignee of the ’958 patent. A copy of the ’958 patent is attached hereto as Exhibit A.

19. B+L is the holder of New Drug Application (“NDA”) No. 203168 for Prolensa[®],

which the FDA approved on April 5, 2013. In conjunction with NDA No. 203168, the '958 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book").

20. Bromfenac ophthalmic solution 0.07% is sold in the United States under the trademark Prolensa®.

AMNEAL'S INFRINGING ANDA SUBMISSION

21. Upon information and belief, Amneal filed or caused to be filed with the FDA ANDA No. 210962, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

22. Upon information and belief, Amneal's ANDA No. 210962 seeks FDA approval to sell in the United States Amneal's generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa®.

23. Plaintiffs received a letter dated October 26, 2018, from Amneal, purporting to be a Notice of Certification for ANDA No. 210962 ("Amneal's notice letter") under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c).

24. Amneal's notice letter alleges that Amneal has submitted to the FDA ANDA No. 210962 seeking FDA approval to sell Amneal's generic bromfenac ophthalmic solution, intended to be a generic version of Prolensa®.

25. Amneal's notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege meritorious non-infringement defenses for any of the claims of the '958 patent.

26. Upon information and belief, ANDA No. 210962 seeks approval of Amneal's generic bromfenac ophthalmic solution that is the same, or substantially the same, as Prolensa®.

COUNT I AGAINST AMNEAL

Infringement of the '958 Patent under § 271(e)(2)

27. Paragraphs 1-26 are incorporated herein as set forth above.

28. Under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '958 patent by submitting, or causing to be submitted to the FDA, ANDA No. 210962 seeking approval for the commercial marketing of Amneal's generic bromfenac ophthalmic solution before the expiration date of the '958 patent.

29. Upon information and belief, Amneal's generic bromfenac ophthalmic solution will, if approved and marketed, infringe at least one claim of the '958 patent.

30. Upon information and belief, Amneal will, through the manufacture, use, import, offer for sale, and/or sale of Amneal's generic bromfenac ophthalmic solution, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '958 patent.

COUNT II AGAINST AMNEAL

Declaratory Judgment of Infringement of the '958 Patent

31. Paragraphs 1-30 are incorporated herein as set forth above.

32. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

33. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

34. Amneal has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Amneal's generic bromfenac ophthalmic solution before the expiration date of the '958 patent, including Amneal's filing of

ANDA No. 210962.

35. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Amneal's generic bromfenac ophthalmic solution will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '958 patent.

36. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Amneal's generic bromfenac ophthalmic solution will constitute infringement of at least one claim of the '958 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Amneal on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Amneal has infringed at least one claim of the '958 patent by submitting or causing to be submitted ANDA No. 210962 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Amneal's generic bromfenac ophthalmic solution before the expiration of the '958 patent;
2. order that the effective date of any approval by the FDA of Amneal's generic bromfenac ophthalmic solution be a date that is not earlier than the expiration of the '958 patent, or such later date as the Court may determine;
3. enjoin Amneal from the commercial manufacture, use, import, offer for sale, and/or sale of Amneal's generic bromfenac ophthalmic solution until expiration of the '958

patent, or such later date as the Court may determine;

4. enjoin Amneal and all persons acting in concert with Amneal from seeking, obtaining, or maintaining approval of Amneal's ANDA No. 210962 until expiration of the '958 patent;

5. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees;

6. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: December 7, 2018
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

William P. Deni, Jr.

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CERTIFICATION OF NON-ARBITRABILITY
PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: December 7, 2018
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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